NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ORTHO-MCNEIL PHARMACEUTICAL, INC., *et al.*, Plaintiffs, v. TEVA PHARMACEUTICALS USA, Defendant.	**OPINION** Civ. No. 02-2794 (GEB) (Lead Case)
ORTHO-MCNEIL PHARMACEUTICAL, INC., *et al.*, Plaintiffs, v. SICOR PHARMACEUTICALS INC., *et al.* Defendants.	Civ. No. 03-5932 (GEB)
DAIICHI PHARMACEUTICAL CO., LTD, Plaintiff, v. HI-TECH PHARMACAL CO., INC. Defendant.	Civ. No. 03-6006 (GEB)

ORTHO-MCNEIL PHARMACEUTICAL, INC., *et al.*, Plaintiffs, v. AMERICAN PHARMACEUTICAL PARTNERS, INC. Defendant.	:	Civ. No. 03-6046 (GEB)
ORTHO-MCNEIL PHARMACEUTICAL, INC., *et al.*, Plaintiffs, v. SICOR PHARMACEUTICALS INC, *et al.*, Defendants.	:	Civ. No. 04-6270 (GEB)

BROWN, C.J.

This matter comes before the Court upon Plaintiffs Ortho-McNeil Pharmaceutical Inc., Johnson & Johnson Pharmaceutical Research & Development, LLC, and Daichii Pharmaceutical Co. Ltd.'s (collectively referred to as "Plaintiffs") Renewed Motion for Summary Judgment of No Inequitable Conduct. The Court, having decided the motion based on the parties' written submissions and without oral argument pursuant to Federal Rule of Civil Procedure 78, and for the reasons discussed herein, grants Plaintiffs' Motion.

I. BACKGROUND

This Court has been asked to revisit its prior ruling of July 6, 2005 wherein the Court

granted-in-part and denied-in-part Plaintiffs' motion for summary judgment that U.S. Patent No. 5,053,407 ("the '407 patent") was not unenforceable due to inequitable conduct committed by the patentees. Oral argument was heard on July 6, 2005, and the Court rendered its decision in the form of an oral opinion on the same day. The Court granted Plaintiffs' motion for summary judgment that the patent was not unenforceable based on the Gerster '85 reference. Additionally, the Court denied Plaintiffs' motion for summary judgment of no inequitable conduct based on certain undisclosed toxicity data, finding that a genuine issue of material fact existed as to the materiality of such data. (Tr. of July 6, 2005 Hr'g at 49:11-50:14).

At the hearing, the Court was also informed of an action in the Northern District of West Virginia concerning the same patent against Mylan Laboratories, Inc. and Mylan Pharmaceuticals, Inc. (collectively referred to as "Mylan"). Mylan was the first generic company to file an Abbreviated New Drug Application ("ANDA") with the Food and Drug Administration ("FDA") pursuant to the Hatch-Waxman Act. *See Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.*, 348 F. Supp. 2d 713 (N.D. W. Va. 2004). In doing so, Mylan sought permission from the FDA to manufacture and distribute generic versions of levofloxacin, the subject of the '407 Patent. After Plaintiffs received notice of Mylan's ANDA filing, Plaintiffs brought suit against Mylan alleging infringement of the '407 Patent. After the completion of an eight-week bench trial, Chief Judge Irene Keeley ("Judge Keeley") rendered a comprehensive Opinion addressing a number of issues regarding the '407 Patent, including inequitable conduct. Judge Keeley found that the '407 Patent was not unenforceable due to inequitable conduct based on the patentees' acts and certain omissions concerning the '85 Gerster reference, as well as data from certain studies conducted on levofloxacin. *Ortho-McNeil,* 348 F. Supp. 2d at 739-48.

Mylan subsequently appealed the final decision to the Court of Appeals for the Federal Circuit. Oral argument was heard at the Federal Circuit on December 7, 2005. On December 19, 2005, less than two later, the Federal Circuit entered a *per curiam* order summarily affirming the judgment of Judge Keeley pursuant to Federal Circuit Rule 36.[1] Mylan's petition for rehearing was denied on March 13, 2006.

Particularly relevant to the present case is Judge Keeley's decision concerning toxicity tests with respect to Mylan's inequitable conduct claim. Based on this Court's July 6, 2005 summary judgment ruling, one issue in this case remains, namely whether the patent applicants acted inequitably by failing to disclose certain toxicity data relating to levofloxacin and ofloxacin. Defendants Teva Pharmaceuticals USA, Inc., Sicor Pharmaceuticals Inc. *et al.*, Hi-Tech Pharmacal Co., Inc., and American Pharmaceutical Partners, Inc. (collectively referred to as "Defendants") argue that the case is not amenable to summary judgment because there are disputed factual issues which must be resolved at trial, notwithstanding the Federal Circuit's affirmance of the *Mylan* decision.

In contrast, Plaintiffs assert that Defendants rely on the same arguments and factual record as the Mylan defendants to support their inequitable conduct claim. Although the defendants in *Mylan* were different defendants than the named defendants here, Plaintiffs further assert that Defendants "conducted joint discovery with the *Mylan* defendants and have no factual evidence that was not before the trial court and the Federal Circuit in *Mylan*." (Pls.' Br. In Supp. of Renewed Mot.

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[1] The Federal Circuit has stated that "a judgment of affirmance without opinion under Fed. Cir. R. 36 . . . is used only when the appellant/petitioner has utterly failed to raise any issues in the appeal that require an opinion to be written in support of the court's judgment of affirmance." (Reply in Supp. of Pls.' Renewed Mot. for Summ. J. of No Inequitable Conduct ("Pls.' Renewed Reply"), Ex. B).

for Summ. J. of No Inequitable Conduct at 4). As such, Plaintiffs assert that the outcome here should be the same as the outcome reached in *Mylan*. The Court will now analyze the effect of Judge Keeley's decision and the Federal Circuit's affirmance of that decision to the present case.

II. DISCUSSION

As a preliminary matter, the Court will address the proper standard to be applied in the instant motion. During the teleconference with the parties which was held on January 4, 2006, Plaintiffs requested, and this Court granted, permission to file a *renewed* motion for summary judgment, in light of the Federal Circuit's affirmance of the *Mylan* decision. (Tr. of Jan. 4, 2006 Teleconference). At that time, Defendants did not assert that the motion should be construed as a motion for reconsideration pursuant to Local Civil Rule 7.1(i), but now characterizes the instant motion as such in their opposition brief. The Court is inclined to treat the motion as a summary judgment motion using the applicable standard under the Federal Rules of Civil Procedure. In particular, the Court will determine whether there exists a genuine issue of material fact that can only be resolved at trial.[2]

A. Standard for Summary Judgment

A party seeking summary judgment must "show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." FED. R. CIV.

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[2] If, however, the Court were to treat the motion as one for reconsideration, the Court would nonetheless reach the same conclusion since the Rule 7.1(i) acknowledges "an intervening change in the controlling law" as grounds for reconsideration. L. Civ. R. 7.1(i); *Carmichael v. Everson,* No. Civ. 03-4787, 2004 WL 1587894 (May 21, 2004 D.N.J. 2004). The Federal Circuit's *per curiam* affirmance of the *Mylan* decision constitutes such an intervening change of law. As such, whether to apply the standard for summary judgment or the standard for reconsideration appears to be a distinction without a difference.

P. 56(c); *see also Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). The threshold inquiry is whether there are "any genuine factual issues that properly can be resolved only by a finder of fact because they may reasonably be resolved in favor of either party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 250 (1986) (noting that no issue for trial exists unless there is sufficient evidence favoring the nonmoving party for a jury to return a verdict in its favor). In deciding whether triable issues of fact exist, the court must view the underlying facts and draw all reasonable inferences in favor of the non-moving party. *Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986); *Pa. Coal Ass'n v. Babbitt*, 63 F.3d 231, 236 (3d Cir. 1995).

B. Plaintiffs' Motion for Summary Judgment of No Inequitable Conduct

To prevail on their inequitable conduct claim, Defendants must prove that the patent applicants failed to disclose or submitted false material information to the Patent and Trademark Office ("PTO") and, in doing so, intended to deceive or mislead. *Abbott Labs. v. TorPharm, Inc.*, 300 F.3d 1367, 1379 (Fed. Cir. 2002). The Court's analysis of inequitable conduct "is performed in two steps comprising first, a determination of whether the withheld reference meets a threshold level of materiality and intent to mislead, and second, a weighing of the materiality and intent in light of all the circumstances to determine whether the applicant's conduct is so culpable that the patent should be held unenforceable." *Ferring B.V. v. Barr Labs., Inc.,* 437 F.3d 1181, 1187 (Fed. Cir. 2006) (quotations omitted). "The predicate facts must be proven by clear and convincing evidence." *Id.*

1. Whether the withheld references meet a threshold level of materiality and intent to mislead

In performing the first step of its inequitable conduct analysis, this Court must determine

whether Defendants have adduced sufficient evidence to meet a threshold level of materiality and intent to deceive. The references at issue concern certain data which, according to Defendants, demonstrate that the patent applicants made a false and misleading statement to the PTO concerning levofloxacin's toxicity during prosecution of the '407 Patent.

a. Materiality

Defendants allege that the applicants acted inequitably by representing to the PTO that levofloxacin was surprisingly less toxic than ofloxacin in an effort to overcome an obviousness rejection during prosecution. Defendants identify three main grounds upon which they make this assertion. First, Defendants assert that the applicants failed to disclose information which Daichii toxicologists obtained demonstrating that levofloxacin and ofloxacin share similar toxicity. (Defs.' Br. in Opp'n to Pls.' Mot. for Summ. J. of No Inequitable Conduct ("Defs.' Original Opp'n") at 7-8). Second, Defendants contend that the applicants failed to disclose certain data that would have cast doubt upon the validity of the LD_{50} comparisons which were submitted to the PTO.[3] (*Id.*). Third, Defendants assert that Daichii failed to disclose acute oral toxicity tests showing that the oral administration of levofloxacin was more toxic than ofloxacin. (*Id.*).

In support of these disputed issues, Defendants submit the expert declaration of Dr. Apostolou, a toxicologist, who opines that failure to present the undisclosed data "deprived the examiner of information crucial to his ability to interpret the data presented and to assess the accuracy of the applicant's portrayal of levofloxacin's toxicity as unexpectedly lower than that of

[3] Defendants assert that: 1) the LD_{50} values submitted to the PTO were taken from studies that were conducted "years apart and under different conditions"; 2) the LD_{50} data did not come from same mortality data reported in Table 3 in the '407 Patent; and 3) there were overlapping confidence intervals in LD_{50} values between levofloxacin and ofloxacin. (*Id.* at 8).

ofloxacin." (*Id.* at 15). Thus, Defendants contend that this undisclosed information was highly material.

In *Mylan*, the defendants made a similar allegation that Plaintiffs "acted inequitably by submitting statistically insignificant toxicity data indicating that levofloxacin was less toxic than ofloxacin." *Id.* at 740. The defendants also argued that "Daiichi failed to submit oral toxicity studies that concluded that levofloxacin was not less toxic than ofloxacin." *Id.* After hearing the evidence, Judge Keeley concluded that "neither the lack of confidence intervals nor the failure to submit oral toxicity data was a material omission." *Id.* at 741. Judge Keeley found that confidence intervals are "not very important" in small studies involving acute toxicity leading to death, and are commonly omitted from reports pertaining to LD_{50} values. *Id*. Thus, Daichii's failure to include confidence intervals in the toxicity data was not deemed a material omission.

Additionally, Judge Keeley discussed the evidence at trial which characterized acute oral toxicity tests as unreliable indicators of inherent toxicity. *Id*. at 742. The evidence established that the presence of confounding factors in oral toxicity tests, such as solubility and absorption rate, affects the precision of a toxicity determination in oral toxicity tests. *Id*. The court noted the weak evidence Mylan presented to the contrary. As such, the court rejected Mylan's argument that Plaintiffs' failure to submit oral toxicity data to the PTO amounted to a material omission. The Federal Circuit subsequently affirmed these findings.

Defendants argue that Judge Keeley's rulings and the Federal Circuit's affirmance do not change this Court's earlier ruling that an issue of fact exists as to whether the withheld information constitutes a material omission. The Court agrees with Defendants on this point. Defendants accurately state that this Court is presented with a different factual record than the record that was

before Judge Keeley. Particularly, in this case Defendants have proffered the expert opinion of a toxicologist, Dr. Apostolou, who opines that the undisclosed toxicity data was highly material. Defendants contend that the only expert testimony concerning toxicology the *Mylan* court received was from Daichii's expert, Dr. Rodricks. Plaintiffs dispute this contention, asserting that "Mylan's lead expert, Dr. Lester Mitchell, was permitted to testify extensively on issues of toxicology." (Pls.' Renewed Reply at 7-8). Because it does appear that Judge Keeley's decision concerning materiality was based on a different factual record, Judge Keeley's ruling and the Federal Circuit's affirmance do not alter this Court's earlier ruling that there is an issue of fact with respect to the materiality prong of the inequitable conduct claim. As such, drawing all reasonable inferences in favor of Defendants as the non-moving party, the Court concludes that Defendants have proffered sufficient evidence to meet a threshold level of materiality.

b. Intent

"Even if an omission is found to be material, the omission must also be found to have been made with the intent to deceive." *Ferring,* 437 F.3d at 1191. In an inequitable conduct claim, the Federal Circuit has made clear that intent to deceive cannot be "inferred solely from the fact that information was not disclosed; there must be a factual basis for a finding of deceptive intent."[4] *Purdue Pharma L.P. v. Endo Pharms.*, Nos. 04-1189, 04-1347, 04-1357, 2006 WL 231480, at *9 (Fed. Cir. Feb 1, 2006) (quoting *Hebert v. Lisle Corp.*, 99 F.3d 1109, 1116 (Fed. Cir. 1996)). To

[4] Contrary to Defendants assertion, this Court did not rule that "an inference of intent to deceive the PTO is appropriate here given the high materiality of the undisclosed information." (Br. in Opp'n to Renewed Mot. for Summ. J. of No Inequitable Conduct at 12). Instead, the Court simply noted that an inference of intent may be warranted "if in fact there is a high degree of materiality." (Tr. of July 6, 2005 Hr'g at 50:5-8). Thus, the Court made no ruling on the issue of intent during the July 6, 2005 hearing.

satisfy this requirement, "the involved conduct, viewed in light of all the evidence, including evidence of good faith, must indicate sufficient culpability to require a finding of intent to deceive." *M. Eagles Tool Warehouse, Inc. v. Fisher Tooling Co., Inc.,* 2006 WL 454355, at *6 (Fed. Cir. Feb 27, 2006) (quoting *Paragon Podiatry Lab. v. KLM Lab*., 984 F.2d 1182, 1189 (Fed. Cir. 1993)).

Based on the record, the Court concludes that Defendants have not proffered sufficient evidence to meet this key requirement. The Court finds the record devoid of any indicia that the patent applicants intended to deceive the PTO by representing that levofloxacin was less toxic than ofloxacin. The evidence Defendants rely upon to establish intent essentially amounts to one of the inventors' general awareness of the undisclosed information which Defendants characterize as material. (Defs.' Original Opp'n at 19). Outside of this, Defendants merely argue that they are entitled to an inference of intent. The law is clear, however, that an inference of intent cannot be solely based on the nondisclosure of information. *Purdue Pharma*, Nos. 04-1189, 04-1347, 04-1357, 2006 WL 231480, at *9. Rather, there must be a factual basis supporting such an inference. *Id.* The Court concludes that Defendants have not proffered sufficient facts demonstrating that the patent applicants harbored any intent to deceive the PTO in light of the additional evidence in the record.

For example, the evidence of record indicates that levofloxacin is in fact less toxic than ofloxacin. (Declaration of Joseph Rodricks in Supp. of Pls.' Mot. for Summ. J. of No Inequitable Conduct ¶¶ 7, 9, 21-27, 42-48, 50-52 & Exs. H-P, R, S-Z); *see also Mylan*, 348 F. Supp. 2d at 751 ("Therefore, the Court finds that levofloxacin is appreciably less toxic than ofloxacin."). Moreover, the record reflects the good faith belief of one of the inventors, Dr. Hayakawa, that levofloxacin was surprisingly less toxic than ofloxacin, and that acute intravenous tests were the best measure of a drug's toxicity. *See M. Eagles Tool Warehouse,* 2006 WL 454355, at *6 (noting that the court must

consider evidence of good faith in its inequitable conduct analysis); (*see also* Hayakawa Decl. ¶¶ 27-29; 30-31 & Ex. 6-9; Hayakawa May 12-13, 2003 Dep. at 168:13-169:2). Additionally, the evidence shows that Dr. Hayakawa did not report confidence intervals in his own reports. (Hayakawa Decl. ¶ 34). Thus, the Court concludes that an inference of deceptive intent is not warranted in light of the surrounding circumstances.

Defendants also advance the argument that an inference of intent must be drawn based on a "pattern of failures to disclose material information relative to toxicity." *Id*. at 21. This same argument, however, was raised by the *Mylan* defendants on appeal, and squarely rejected by the Federal Circuit. On appeal, the *Mylan* defendants argued that intent should be inferred from the high materiality of the undisclosed information, and further argued that a pattern of "selective disclosure clearly evinces an intent to mislead and constitutes inequitable conduct." *See* Appellate Br. of Defs.-Appellants Mylan Labs. Inc. and Mylan Pharms. Inc., 2005 WL 1178168, at 67 (Apr. 15, 2005); Appellate Reply Br. of Defs.-Appellants Mylan Labs. Inc. and Mylan Pharms. Inc., 2005 WL 1868567, at 26-30 (July 5, 2005). By affirming the decision of the district court, however, the Federal Circuit rejected both of these arguments. As such, this Court likewise concludes that Defendants' argument fails.[5]

Lastly, Defendants argue that an inference of intent should be drawn based on the high

[5] Defendants include as part of this alleged selective disclosure certain representations that were made to the FDA which were not made to the PTO. This same argument was indeed raised before Judge Keeley which she ultimately rejected in light of the different standards for disclosure required by the two agencies. *See Ortho-McNeil,* 348 F. Supp. 2d at 742 & n.15. The *Mylan* defendants raised this issue on appeal, which was rejected by Federal Circuit. *See* Mylan's Appellate Br., 2005 WL 1178168, at 67; Mylan's Appellate Reply Br., 2005 WL 1868567, at 29-30. In light of the guidance provided by both of these decisions, the Court rejects this argument.

materiality of the undisclosed information. Defendants' argument is flawed for two reasons. First, this argument presumes that the materiality of the undisclosed information was particularly high. Such a presumption is unwarranted. Although the Court concluded above that Dr. Apostolou's expert opinion creates disputed issues of fact with respect to materiality, the evidence of the record, along with Judge Keeley's finding that nondisclosure of certain toxicity test results did not amount to a material omission, much less a highly material omission, as well as the Federal Circuit's affirmance of this conclusion, suggest the absence of high materiality. Second, even if a factfinder concludes that the omission was highly material, the Court still finds that Defendants have not identified a proper factual basis to support such an inference that the patent applicants intended to deceive the PTO. Thus, although all reasonable inferences must be drawn in favor of the non-movant at summary judgment, the Court does not find that a reasonable inference of deceptive intent is warranted here given the lack of clear and convincing evidence of culpable conduct by the patent applicants.[6]

Accordingly, the Court concludes that Defendants have not adduced sufficient evidence from which a factfinder could conclude that the requisite elements of inequitable conduct can be established by clear and convincing evidence. In light of Defendants failure to meet its high burden, the Court grants summary judgment in favor of Plaintiffs.

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[6] Citing *Refac International, Ltd. v. Lotus Development Corp.*, 81 F.3d 1576 (Fed. Cir. 1996), Defendants also contend that an inference of intent is proper because the PTO did not have the ability to obtain the undisclosed information on its own. This case, however, does not remove the basic requirement that a factual basis must exist before an inference of deceptive intent may be drawn. Because Defendants fail to establish such a factual basis, this argument fails.

2. Whether the applicant's conduct is so culpable that the patent should be held unenforceable

Assuming *arguendo* Defendants made a threshold showing of materiality and intent to mislead, the Court would nonetheless grant summary judgment in favor of Plaintiffs in light of the second step of the inequitable conduct analysis. Once threshold showings of materiality and intent are established, the Court must balance "materiality and intent to determine whether the equities warrant the conclusion that inequitable conduct occurred. In light of all circumstances, an equitable judgment must be made concerning whether the applicant's conduct is so culpable that the patent should not be enforced." *Semiconductor Energy Lab. Co., Ltd. v. Samsung Elecs. Co., Ltd.*, 204 F.3d 1368, 1372 (Fed. Cir. 2000) (citation and quotations omitted).

In the present case, the evidence of the record does not demonstrate that the the patent applicants acted with the degree of culpability that would tilt the scales in favor of a finding of inequitable conduct. Defendants' inequitable conduct claim is based on the nondisclosure of certain information which Judge Keeley and the Federal Circuit already concluded did not amount to a material omission. Moreover, the record reflects the applicant's good faith belief that levofloxacin exhibited a lower toxicity than ofloxacin and the tests relied upon by the applicants were the best measure of the drug's toxicity. Defendants have not identified any actions taken by the patent applicants which this Court deems so egregious that the patent should be rendered unenforceable.

III. CONCLUSION

In light of the foregoing analysis, Plaintiffs' renewed motion for summary judgment is granted. An appropriate form of Order accompanies this Memorandum Opinion.

s/ Garrett E. Brown, Jr.
GARRETT E. BROWN, JR., U.S.D.J.

Date: March 17 , 2006